Manual for the Completion of CDISC Aligned NCI Standard Case Report Form (CRF) Modules

Introduction

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into four categories:

- Mandatory – A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- Conditional – A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- Optional – A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.
- Non-harmonized – A data collection variable that is, by consensus, to primarily belong to a different CRF module or is not belonging to any defined module.

A template form with modules that contain questions or variables representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc. Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

Screening CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

This NCI Standard Template Form maps to the following domains in the CDASHIG v2.0 metadata table:

- DS – Disposition (v2.0)
- IE – Inclusion/Exclusion Criteria Not Met (v2.0)

Mapping to the SDTM:

This NCI Standard Template Form maps to the following domains in the SDTMIG v3.3 metadata table:

- DS – Disposition (v3.3)
- IE – Inclusion/Exclusion Criteria Not Met (v3.3)

Screening CDISC Aligned NCI Standard Template Module Template Instructions

Field Descriptions and Instructions

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Trial Screening Criterion Fulfill Indicator (m) 6974988 IEMTALNY	An indication whether or not the trial screening criteria was fulfilled. CDASH: IEYN (6408651); SDTM: No Match	CHARACTER. Use choice list.
Trial Screening Criterion Negation Fulfill Text (o) 6974989 IECRTNMT	The description of the trial criteria that were not fulfilled. CDASH: IETESTCD (6421480) and IETEST (6421481); SDTM: IETESTCD (No CDE) and IETEST (No CDE)	CHARACTER
Eligibility Determination Checklist Version Date (o) 2960683 ELIG_DT_CKLST_VER_DT	The date of the version of the Eligibility Checklist that was used in determining eligibility. Not for FDA submission	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Trial Screening Complete Date (o) 6974991 DSSRCMDT	The date trial screening was completed, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSTERM (6355980) and DSSTDAT (6384212) where DSTERM (6355980) = "SCREEN COMPLETED"; SDTM: DSSTDTC (No CDE) where DSTERM (No CDE) = "SCREEN COMPLETED"	DATE

Annotated CRF: Screening CDISC Aligned NCI Standard Template

This annotated CRF is ONLY used to show CDISC mapping without consideration of the CRF layout. CDASH mapping is in **Blue**, and SDTM mapping is in **Red**.

Form Name: Screening CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Does the participant meet all screening criteria? (6974988) **CDE Short Name:** IEMTALNY CDASH: IEYN (6408651) SDTM: No Match	CHARACTER – Maximum Length = 2 ☐ N – No ☐ NA – Not Applicable ☐ U – Unknown ☐ Y – Yes

Optional Questions

CRF Question	Value Domain
If not, which screening criteria not met? (6974989) **CDE Short Name:** IECRTNMT CDASH: IETESTCD (6421480) and IETEST (6421481) SDTM: IETESTCD (No CDE) and IETEST (No CDE)	CHARACTER – Maximum Length = 200
Checklist Version Date (2960683) **CDE Short Name:** ELIG_DT_CKLST_VER_DT CDASH: Not for FDA submission SDTM: Not for FDA submission	DATE – Maximum Length = 12
Screen Completion Date (6974991) **CDE Short Name:** DSSRCMDT CDASH: DSTERM (6355980) and DSSTDAT (6384212) where DSTERM (6355980) = "SCREEN COMPLETED" SDTM: DSSTDTC (No CDE) where DSTERM (No CDE) = "SCREEN COMPLETED"	DATE – Maximum Length = 11